May 29, 1962 A. E. KRUG 3,036,700

STERILE HYPODERMIC NEEDLE ASSEMBLY AND PACKAGE

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FIG. 1

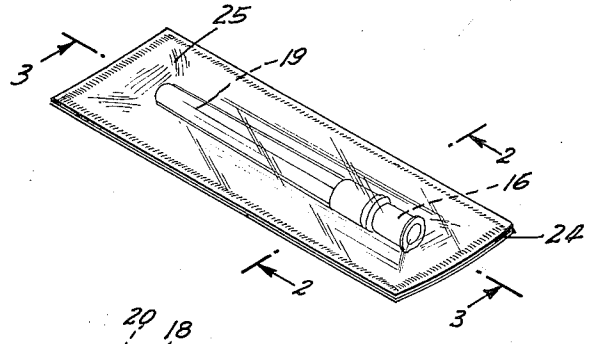

FIG. 2

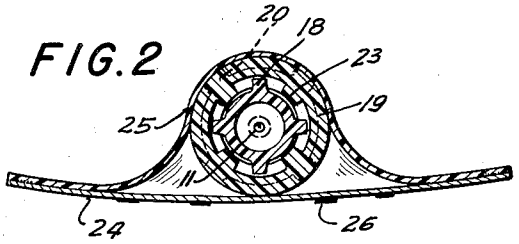

FIG. 3

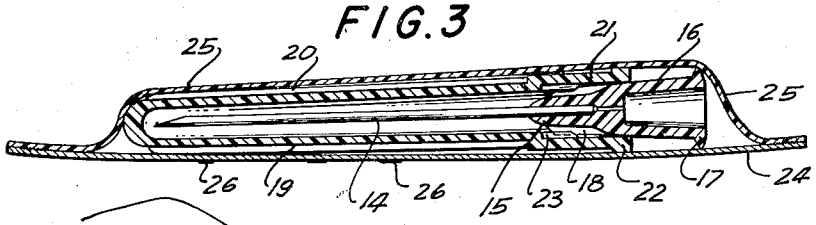

FIG. 4

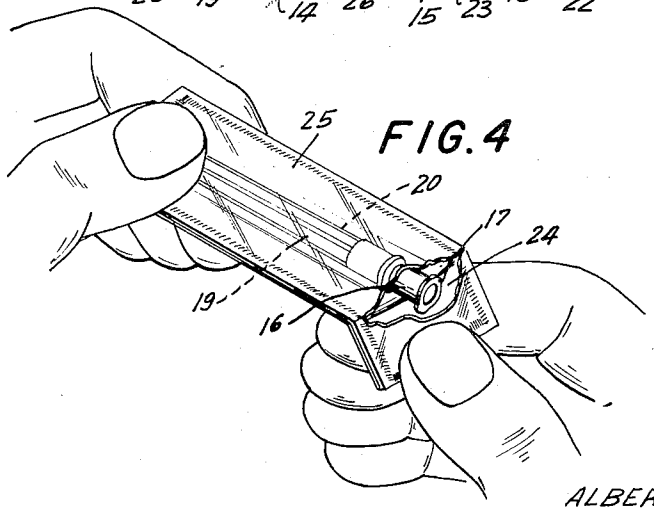

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FIG. 5

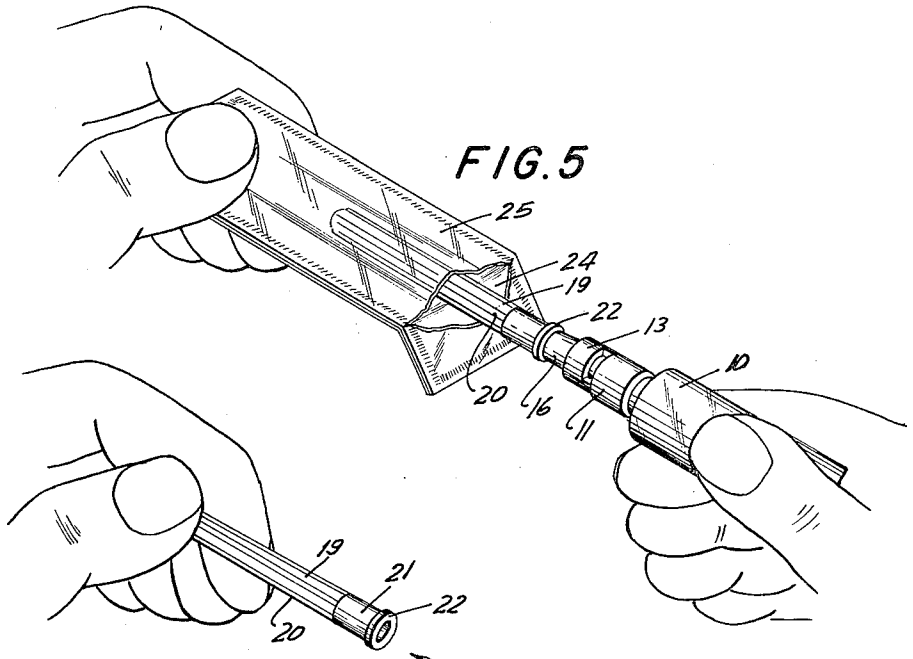


FIG. 6

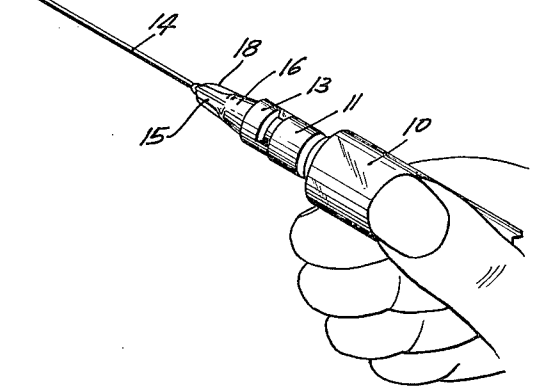
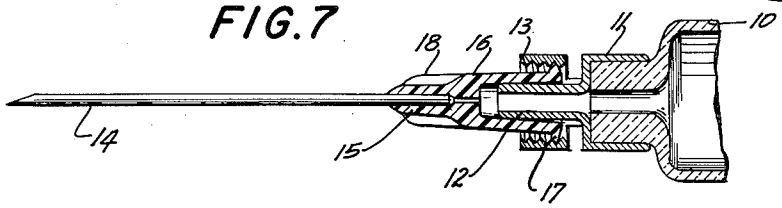


FIG. 7



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3,036,700 STERILE HYPODERMIC NEEDLE ASSEMBLY AND PACKAGE

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6 Claims. (Cl. 206—43)

This invention relates to a structurally and functionally improved hypodermic needle assembly and package structure whereby that needle assembly will be maintained in sterile condition until it is used by a physician or nurse.

Additionally, the needle assembly may be mounted upon the tip of a syringe barrel without contamination of its operative parts, so that complete sterility and freedom from the danger of infection are assured.

A further object is that of designing a structure of this type which will present a neat and attractive appearance and will enable the user to inspect the contained needle assembly; that assembly being capable of being readily mounted upon a syringe barrel and remaining—insofar as its operative parts are concerned—in sterile condition up to the time that the injection is to be performed.

With these and other objects in mind, reference is had to the attached sheets of drawings illustrating one practical embodiment of the invention, and in which:

FIG. 1 is a perspective view of the entire package assembly;

FIG. 2 is an enlarged transverse sectional view taken along the line 2—2 in the direction of the arrows as indicated in FIG. 1;

FIG. 3 is a sectional side view taken along the line 3—3 in the direction of the arrows as indicated in FIG. 1;

FIG. 4 is a perspective view of the package in process of being opened;

FIG. 5 illustrates the needle assembly as applied to a syringe barrel;

FIG. 6 is a similar view showing the detachment of the sheath from that assembly; and

FIG. 7 is an enlarged and fragmentary sectional view showing the needle in mounted position upon a syringe tip.

Referring primarily to FIG. 7, the numeral 10 indicates the outer end of a syringe barrel mounting any proper type of tip assembly or otherwise providing a tip to receive the hub of the hypodermic needle. As shown, the fitting 11 includes a tip portion 12 and an interiorly threaded collar 13, thus providing a Luer coupling. A hypodermic needle 14 is supported on the outer end of the syringe barrel and includes a hub embracing a reduced tip portion 15 and an enlarged portion 16. Both these parts are bored to provide a passage between the lumen of the needle and the interior of the syringe barrel. The bore of the enlarged portion 16 is preferably tapered, and at its rear end has outstanding projections or flanges 17 for engagement with the threads of collar 13 to thus hold the needle in operative association with the barrel.

The outer face of the enlarged portion 16 of the hub is preferably tapered in the direction of the needle point. Also, it is free from any projections around its entire circumference. Radially extending ribs 18 are integral with the hub and are disposed in the zone of the reduced tip portion 15. These ribs may have their outer edges inclined in the direction of the needle point to extend in line with the surface of the enlarged portion 16.

The needle is enclosed by a sheath, a sectional side view of which is shown in FIG. 3. In that view the numeral 19 indicates the body of the sheath, which is formed of an impervious material, preferably of a transparent or translucent nature. Conveniently, ribs 20 extend outwardly

from the exterior surface of the sheath. The rear or open end of the sheath is defined by a thickened zone 21 conveniently terminating in a collar portion 22. Within this thickened area and spaced inwardly from collar 22, the bore of the sleeve is provided with inwardly projecting parts 23. These parts are spaced from each other to define between them recesses, as shown in FIG. 2.

Thus, with ribs 18 disposed within these recesses, it follows that rotation of the needle and its hub with respect to the sheath may not occur, because with any such tendency of the parts, the ribs 18 will strike against the side walls of projections 23. Also, it will be observed that with the sheath disposed as in FIG. 2, a completely effective seal will be provided between the bore surface of the sheath and the enlarged portion of the hub. This seal will come into being in the zone of collar 22, which intimately engages the outer and tapered surface of hub portion 16. That surface is free from interruption throughout its entire circumference, as is also the bore surface defined by the zone of the collar. Therefore, there will be no danger of air flowing past the hub to enter the space within the sheath bore, with possible contamination of the needle 14.

The needle assembly thus provided forms a part of the complete package. That package, as especially shown in FIGS. 1 to 4, includes a base 24 and a cover 25. Both of these embrace sheets of material, which in the case of the base may be book-type paper with a coating of vinyl applied in the form of a pattern 26 such that intervening spaces exist. Through these gaps in the coating, gas may pass through the material of base 24. The cover portion 25 is formed of a suitable acetate with a sizing of vinyl chloride. The areas of the sheets 24 and 25 are such that with their marginal edge zones sealed together by, for example, heat and pressure in accordance with well-known techniques, the central portion of the cover extends upwardly to furnish an enclosure of an area adequate to receive the needle assembly and flaring in the direction of its hub. Also, the length of that enclosure will be just adequate to accommodate such assembly.

With the sheath materials providing the base and cover being flexible but having a definite tendency to retain their initial configurations, it is apparent that the parts will be under tension. This will be because the needle and sheath asembly will intimately bear against the inner surfaces defining the enclosure. It follows that the parts will tend to curl slightly, as in FIGS. 1 and 2, due to the tension which will exist. The edge of the enlarged hub portion 16, whether defined by projections, a flange 17 or otherwise, will lie adjacent the inner face of cover 25.

As will be understood, the parts of the needle assembly and sheath are cleaned and sterilized. Thereupon, these elements are assembled in the manner shown especially in FIG. 3. So assembled, they will be disposed between the sheets providing the base 24 and cover 25. Those sheets will be marginally sealed to each other to furnish the desired container snugly embracing the needle assembly. Gas sterilization may now be resorted to, so that the interior of the enclosure presents no danger of infection. The material of the base will act as a bacterial filter, in the event that air seeps through that base into the enclosure. It is thus apparent that a package assembly is provided which, when once prepared, will maintain the parts in sterile condition for indefinite periods during storage and ordinary handling.

Now, when the needle assembly is to be used, a syringe will of course have been rendered available, and that syringe will be in a condition such that its interior and tip zone is sterile. The user will grasp the package as in FIG. 4. A flexing stress will be imparted to the zone of the base beyond the hub. The material of the cover 25 will be relatively brittle or severable. Therefore, with the

end portion of the package bent down as illustrated, the edge of the hub will bear against the inner surface of the covering. This will result in the rupture of the cover, as also shown in FIG. 4. Of course, other methods of opening the package may be resorted to.

In any event, grasping the material of the package, as shown in FIG. 5, a syringe will be brought to a position adjacent the zone of rupture. By slightly compressing that portion of the package which still encloses the needle assembly, a firm grip may be maintained on the sheath, and consequently, the needle and its hub may likewise be retained. The enlarged portion of the hub will be presented to the tip of the syringe barrel, and relative rotation of the parts will be resorted to, so that the sheath and needle turn as a unit with respect to the syringe tip or tip assembly. This will assure a firm seating of the needle on the barrel tip and the retention of that needle by the barrel.

It should be borne in mind that during this operation the seal between the sheath and hub remains airtight. Therefore, the needle enclosed within that sheath remains sterile. The enclosure provided by base **24** and cover **25** may readily be withdrawn, as in FIG. 5, due to the flaring of the housing space. If desired, the sheath may be left in position on the needle as the latter remains mounted by the barrel. Under these circumstances, contamination will be avoided. Finally, however, by a direct pull on the sheath away from the syringe barrel, as shown in FIG. 5, the needle is exposed. At this time the syringe may be filled and an injection performed.

Thus, among others, the several objects of the invention as specifically aforenoted are achieved. Obviously, numerous changes in construction and rearrangements of the parts may be resorted to without departing from the spirit of the invention as defined by the claims.

I claim:

1. A sterile hypodermic needle assembly and package comprising in combination a hypodermic needle, a hub secured thereto, a sheath enclosing said needle and having an open end zone sealingly engaging said hub at a point short of the end of the latter, sheet material providing a sealed enclosure for said needle and sheath, said enclosure being subject to flexing in an area aligned with the end of the hub exposed beyond said sheath and thus contacting the edge defining said hub end, whereby under flexing of said closure and under consequent increasing contact pressure against the internal surface of the same by said hub edge, said enclosure will rupture to thus expose, beyond the material of said enclosure, the hub end for application to and retention by the tip of a syringe and the thus mounted sheath and needle being withdrawable from said enclosure as the syringe is shifted from a position adjacent the same without destroying the seal between said sheath and hub.

2. In an assembly as defined in claim 1, the needle and sheath enclosing the same presenting a configuration flared in the direction of said hub to facilitate withdrawal of the needle and sheath therefrom.

3. In an assembly as defined in claim 1, the enclosure being also flexible in the area of the sheath whereby digital gripping pressure against the sheet material in that area will cause the sheath to be maintained against rotation with respect to said enclosure and means for preventing relative rotation between said sheath and hub whereby, under continuing pressure against the sheet material and the contained sheath, the exposed hub end and sheath may be rotated under continuing pressure relative to the tip of a syringe to secure the same to the latter.

4. In an assembly as defined in claim 1, the sheet material providing said enclosure including a base and a cover secured to each other and the material of said cover being brittle and subject to rupture by said hub.

5. In an assembly as defined in claim 4, said base being formed of material having the characteristics of a bacterial filter.

6. In an assembly as defined in claim 5, the cover material being transparent and impervious to gas.

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